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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,992	04/18/2001	Hui Tian	18781-006020	8880
20350	7590	11/19/2003		
TOWNSEND AND TOWNSEND AND CREW, LLP				
TWO EMBARCADERO CENTER				
EIGHTH FLOOR				
SAN FRANCISCO, CA 94111-3834				
			EXAMINER	
			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/837,992

Applicant(s)

TIAN ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 19-30 and 33-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 31, 32 and 75-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Claims 1-18, 31, 32, and 75-77 are under consideration in this Office Action.

#### *Claim Objections*

2. Claims 1-18, 31, 32, and 75-77 are objected to because of the following informalities: Claims 1-18, 31, and 32 are objected to because they recite non-elected subject matter, specifically, SEQ ID NOS: 5 and 6. Applicant is required to cancel the claims or amend the claims to recite the elected subject matter of SEQ ID NO: 3 and SEQ ID NO: 4.

#### *Claim Rejections - 35 U.S.C. § 101*

3. 35 U.S.C. 101 reads as follows:  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-18, 31, 32, and 75-77 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants' arguments filed 8/26/2003 have been fully considered but they are not persuasive. Applicants' position is that the claimed invention is useful and that the utility is specific, substantial, and credible. The Examiner disagrees for reasons of record and reasons stated below.

The specification discloses the nucleotide sequence of SEQ ID NO: 4 and the deduced amino acid sequence of the protein encoded as SEQ ID NO: 3. The specification states that "it is speculated that SSG acts to effect sterol transport activity" (see p. 9, lines 4-5 ). The specification further states that it is speculated that patients with sitosterolemia have a mutation in the SSG moiety of the SSG-ABC8 heterodimer which is speculated to cause sterol efflux from cells (see p. 9, lines 14-27).

The specification does not specifically demonstrate the **specific** function of the protein of SEQ ID NO: 3 as an ATP-binding cassette (ABC) family sterol transporter or its relationship to any disease. Hence, it appears that the main utility of the nucleic acid and protein is to carry out further research to identify the specific biological function and possible role of the claimed

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invention in sitosterolemia.

While the claimed invention can be used in gene and protein expression monitoring experimentations and the productions of antibodies, the specification does not teach any meaningful interpretation of data collected from such experimentations. Nor does the specification teach how to use any identified compound which modulates the expression of the claimed invention.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18, 31, 32, and 75-77 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-18, 31, 32, and 75-77 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the claims encompass any isolated nucleic acid encoding any SSG polypeptide comprising any amino acid sequence that is at least 70% identical to SEQ ID NO: 3, any isolated nucleic acid comprising a nucleotide sequence at least about 70% identical to SEQ ID NO: 4, or any nucleic acid which hybridizes under moderately stringent or stringent hybridization conditions to SEQ ID NO: 4 which is not enabled by the specification for reasons of record.

7. Claims 1-18, 31, 32, and 75-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention.

Applicants' arguments filed 8/26/2003 have been fully considered but they are not persuasive. Applicants' position is that the specification provides both the function(s) and structure(s) of the claimed SSG nucleic acid and polypeptides. The Examiner disagrees for the reasons of record and the reasons stated below.

The claims are directed to any isolated nucleic acid encoding any SSG polypeptide comprising any amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to SEQ ID NO: 3, any isolated nucleic acid comprising a nucleotide sequence at least about 70% identical to SEQ ID NO: 4, or any nucleic acid which hybridizes under moderately stringent or stringent hybridization conditions to SEQ ID NO: 4. The specification defines "SSG polypeptide" as a transporter with the amino acid sequence of SEQ ID NO: 3, or any derivative, homolog, or fragment thereof. The specification does not provide a written description of the specific function and structure of any derivative, homolog, or fragment thereof as encompassed by the term "SSG polypeptide" other than the polypeptide consisting of the amino acid sequence of SEQ ID NO: 2.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite that the claimed nucleic acid encodes an "ATP-binding cassette (ABC) family sterol transporter" may overcome the rejection.

### ***Conclusion***

8. No claim is allowed.


9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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